Johnson & Johnson

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New Brunswick, N.J.

January 18, 1974

Subject: Talc/Asbestos
Meeting with Commissioner Schmidt, FDA
January 16, 1974

Memo to File

Attendees:

for FDA: Dr. V. Wodicka, Director, Bureau of Foods
Dr. H. Eiermann,* Director, Division of Cosmetics Technology.
Mr. J. Wenninger, Deputy Director, Division of Cosmetics Technology.

Later: Commissioner Schmidt and the above.

for J&J: Dr. R. Fuller, Dr. G. Hildick-Smith, Dr. W. Nashed

A preliminary meeting with Dr. Wodicka and his staff was held. We traced the history of the talc/asbestos problem: Kretchmer letter; FDA Symposium, August, 1971, where Mt. Sinai people admitted that their analysis based on optical microscopy of our product was wrong and that Johnson & Johnson Baby Powder was the best talc available; and we mentioned the voluminous data which we had shared with the FDA. Dr. Eiermann and Mr. Wenninger corroborated our presentations to Dr. Wodicka.

Dr. Eiermann then said that he has reviewed the CTFA Round-Robin test results with his microscopist, Mr. Schulze, and said that Mr. Schulze still thinks the method is valid. We pointed out that we believe that the method has some basic flaws as outlined in the CTFA comment; however, we believe that a cooperative program between FDA and industry should result in a practical solution to the problem.

* Former J&J employee in Brazil.

Plaintiff's Exhibit 2456

We pointed out that we had developed a DTA method capable of measuring 1% chrysotile and we also believe that a step scan x-ray method can be used to detect 0.2% tremolite.

Dr. Eiermann said that they have obtained DTA equipment and x-ray equipment and that he has some reservation about allowing 1% chrysotile.

We volunteered to cooperate with his scientists in the development of the method for DTA and promised to provide a copy of a proposed publication regarding this method.

Dr. Eiermann said that his main interest at this time is to find what level of dust exposure occurs in the process of dusting a baby and that they would like to use the data to calculate allowable asbestos using 5 fibers per ml (OSHA limit) for safe exposure in the mines. We promised to provide a report on the talc dust exposure of babies. We pointed out that the data we have is based on exaggerated dusting of a whole can of baby powder and that the amount generated, namely 345 mg/ m^3 may be excessive. We said that we are currently attempting to make the same calculation he proposed to the data. Our very preliminary calculation indicates that substantial asbestos can be allowed safely in a baby powder.

Dr. Wodicka appeared skeptical of Dr. Eiermann's approach to the problem. He implied that what is safe for a miner may not be safe for a baby.

Dr. Eiermann also mentioned that they were carrying out some studies in-house using an air sampler to assess the dust exposure and were having some difficulties in determining it.

Dr. Hildick-Smith reviewed the current knowledge on the biology of talc and indicated that talc had a low order of toxicity when evaluated in cell culture systems, that animal studies had been conducted which confirmed the cell culture studies, and that long-range inhalation studies in rats by MRC and in hamsters by J&J were being conducted in England and in the U.S.A. and that the results will be available in 1975. It was pointed out that two separate epidemiological studies had been conducted on talc miners, one by Dr. Kleinfeld and the other by Dr. Green at the University of Vermont School of Medicine in Burlington. The data obtained from both studies indicated that, where miners in the Kleinfeld study had been exposed to talc dust for an average of about 17 years and in the Green study for about 7 years, there appeared to be no significant impairment of the miners' health. Utilizing these data, the known information

concerning the amount of talc to which infants were exposed and their respiratory capacity, miners were exposed for a period of approximately 1,000 times that of an infant. The dose respired by the miner is approximately 11,000 times that respired by the infant. It was brought out that critical review of all the world literature failed to show any evidence of adverse health effects following the normal use of cosmetic talcs.

Dr. Hildick-Smith indicated that he was writing a review article on talc and that a copy of the manuscript would be sent to the FDA for their files.

Dr. Fuller stressed Johnson & Johnson's policy of full cooperation with FDA and that if the results of any scientific studies show any question of safety of talc, Johnson & Johnson will not hesitate to take it off the market.

A meeting was then held in Dr. Schmidt's office. The proceedings were similar to that which took place in Dr. Wodicka's office .

Dr. Schmidt asked for information on our Vermont mine: location (Windsor, Vt.), kind of talc (platey talc), processing (froth flotation to maximize platey talc). He wanted to know whether we sell our talc to other companies (cosmetic beneficiated grade is not sold to other companies; other locations in the Windsor mine are used to supply industrial grade talc).

Dr. Fuller pointed out that our meeting is not a "crisis" meeting. The Commissioner appeared to appreciate that. Dr. Fuller again stressed Johnson & Johnson's pplicy of full cooperation with the FDA which preceded the Kretchmer incident, namely, the Tenovus report where Dr. Hildick-Smith had called Dr. Simmons at the time we first heard of it. We reviewed briefly the Tenovus data (unreliable talc particle identification technique, presence of mineral particles in the tissue-fixing baths, lack of formal education of the principal investigator).

Dr. Hildick-Smith also commented briefly on the article relating stomach cancer in the Japanese and pointed out that this was generally discredited by scientists and that there was no information in the world literature or in animal studies completed to indicate talc produced cancer.

Dr. Schmidt said that the FDA could come under pressure from consumer or other groups and that they were particularly vulnerable when there were minimal, inadequate or no scientific data in a specific area. He had, however, developed a tactic by which he publishes in the Federal Register any scientific attack on the FDA in the hope that members of the scientific community could provide data to assist the FDA.

He appreciated the Johnson & Johnson visit and our expression of interest to assist the FDA where possible. He welcomed the opportunity of having a source of scientific information on which he could rely if the occasion arose. He indicated the immediate interest of the FDA in developing a method for assessing asbestos in talc. He pointed out that additional information being developed by Johnson & Johnson and others would meet the possible future need if talc per se is attacked. As there were some scientific data and good scientific studies in hand, the scientific community would be well prepared to withstand any onslaught concerning talc.

The meeting ended on a very cordial note and appreciation by the FDA officials of Johnson & Johnson's visit and willingness to cooperate with the agency in developing methods and providing information concerning talc technology.

G. Hildick-Smith

W. Nashed

cw

cc: Dr. R. A. Fuller
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Mr. D. D. Johnston
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